

AWARD NUMBER: W81XWH-16-1-0581

TITLE: Development, Reliability, and Equivalence of an
Alternate Form for the CQ Duty Performance-based Measure

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Minneapolis, MN 55407

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14. ABSTRACT Previous research demonstrated that the recently-developed Charge of Quarters Duty Test (CQDT), a performance-based assessment of executive function, can be reliably administered and distinguishes between known-groups of healthy control soldiers and those with traumatic brain injury. As such, the CQDT shows promise in helping to inform readiness to return to duty and need for rehabilitation. However, performance based assessments that involve multitasking such as the CQDT, cannot be repeated as a post-treatment outcome measure due to learning effects. Therefore, an equivalent alternate form is needed. <u>Research Question #1.</u> Can an expert team of military, Veterans Administration, and civilian rehabilitation researchers and clinicians develop an equivalent alternate form of the CQD that is experienced as novel by SM with mTBI? <u>Research Question #2.</u> To what extent can 2 independent raters achieve acceptable levels of inter-rater reliability in scoring subject performance of CQD-Original (CQD-O) and CQD-Alternate Form (CQD-AF)? <u>Research Question #3.</u> To what extent is the CQD-AF equivalent to the CQD-O based on a) difference of paired scores for both forms of the CQD and b) correlation between participants' performance of neurocognitive measures of executive functioning and each version of the CQD?					
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1. INTRODUCTION: Narrative that briefly (one paragraph) describes the subject, purpose and scope of the research.

Many Service Members (SM) experience concussion (also known as mild traumatic brain injury [mTBI]) as a result of military combat and training, motor vehicle crashes, and sports-recreational activities. After mTBI, SM may experience an array of sensorimotor and cognitive problems, including difficulty with executive functions. Executive functions refer to higher order thinking abilities that enable goal-directed behavior, particularly in novel situations where people lack well-learned behaviors to draw upon. Because there are evidence-based cognitive rehabilitation interventions that can improve executive functioning, it is important to identify SM with mTBI with executive dysfunction who should be referred to these services before resuming high-consequence activities such as military duty. Unfortunately, executive dysfunction often goes undetected because traditional neurocognitive measures are designed to evaluate single domains rather than integrated functioning and the high levels of structure inherent in these assessments fail to adequately challenge the impaired functions. Performance-based assessment requires the patient to perform tasks that simulate the demands of everyday activities while the examiner uses behaviorally-based metrics to quantify functioning. **Performance-based measures designed to incorporate multitasking appear to be particularly sensitive to detecting deficient executive functions.** Existing performance-based involving multitasking have demonstrated sensitivity to executive dysfunction but the nature of the task components may lack face validity for SM with mTBI and their superiors, especially as related to readiness for return to duty.

Previous research demonstrated that the recently-developed Charge of Quarters Duty Test (CQDT), a performance-based assessment of executive function, can be reliably administered and distinguishes between known-groups of healthy control soldiers and those with traumatic brain injury. As such, the CQDT shows promise in helping to inform readiness to return to duty and need for rehabilitation. However, performance based assessments that involve multitasking such as the CQDT, cannot be repeated as a post-treatment outcome measure due to learning effects. Therefore, an equivalent alternate form is needed.

Research Question #1. Can an expert team of military, Veterans Administration, and civilian rehabilitation researchers and clinicians develop an equivalent alternate form of the CQD that is experienced as novel by SM with mTBI?

Technical Objective #1: Develop an alternate form of the CQD.

Research Question #2. To what extent can 2 independent raters achieve acceptable levels of inter-rater reliability in scoring subject performance of CQD-Original (CQD-O) and CQD-Alternate Form (CQD-AF)?

Technical Objective #2: Assure rater agreement across 2 raters.

Research Question #3. To what extent is the CQD-AF equivalent to the CQD-O based on a) difference of paired scores for both forms of the CQD and b) correlation between participants' performance of neurocognitive measures of executive functioning and each version of the CQD?

Technical Objective #3: Evaluate equivalence of CQD-AF.

2. KEYWORDS: Provide a brief list of keywords (limit to 20 words).

Mild traumatic brain injury symptom complex
Executive function
Performance-based assessment
Multitasking
Alternate form

3. ACCOMPLISHMENTS: The PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency Grants Officer whenever there are significant changes in the project or its direction.

What were the major goals of the project?

List the major goals of the project as stated in the approved SOW. If the application listed milestones/target dates for important activities or phases of the project, identify these dates and show actual completion dates or the percentage of completion.

Table 1. Goals, milestones, and status based on 9-30-2016 SOW

Updated 10-16-17	Estimated, Updated Timeline	Status	% of Study Activities Completed
Technical Objective 1: Develop a CQD-AF			
Subtask 1: Establish contracts and critical documents for all participating institutions, contracts, and consultants	Oct. -Nov. 2016	Completed	100%
Subtask 2: Obtain Allina Health IRB and ORP/HRPO approval to conduct study	Nov. 2016 – Dec. 2017	Completed for Part 1; not started for Part 2	50%
Develop and submit research protocol to the Allina Health IRB for Part 1 (<i>CQD-AF development</i>) (formal data collection for all technical objectives to occur only at CKRC)	Nov. – Dec. 2016	Completed	100%
Once approved by the Allina Health IRB, submit protocol to USAMRMC Office of Research Protections for Part 1, as needed.	May 2017	Completed	100%
Develop and submit research protocol to the Allina Health IRB for Part 2 (<i>CQD-AF validation</i>) (formal data collection for all technical objectives to occur only at CKRC)	Jan. – Feb. 2018	Not started	0%
Once approved by the Allina Health IRB, submit protocol to USAMRMC Office of Research Protections for Part 2, as needed.	Jan. – Feb. 2018	Not started	0%
Order supplies: CQD-O test materials, camcorder	Nov. 2016	Completed	100%
Create study database for Part 1	Feb.-May. 2017	Completed	100%
Create study database for Part 2	Oct. – Nov. 2017	Not started	0%
Subtask 3: Characterize CQD-O			
Finalize CQD-O task analysis methodology	Nov. 2016 – Jan. 2017	Completed	100%
CQD-O document review; administration of CQD-O for experiential analyses	Nov. 2016 – Jan. 2017	Completed	100%
Recruit volunteers at CKRI; video-record performance of CQD-	July 2017	Completed	100%
Hierarchical and cognitive task analyses based on video-recorded performance of CQD-O	August 2017	Completed	100%
Subtask 4: Develop an optimal CQD-AF			
Team work groups generate, develop options for CQD-AF	Oct. – Nov. 2017	Not started	0%
Identify 2 best CQD-AF options; reduce to practice and informally administer (no formal data collection)	December 2017	Not started	0%
Team consensus meeting to select optimal version of CQD-AF for subsequent evaluation and to finalize Phase 2 protocol	January 2018	Not started	0%

Technical Objective 2: Assure rater agreement across 2 raters				
Subtask 1: Recruit and consent up to 15 participants		March 2018	Not started	0%
Subtask 2: Administer CQD-O and CQD-AF to up to 15 participants to verify interrater reliability with 2 raters				
Technical Objective 3: Evaluate equivalence of CQD-AF				
Subtask 1: Recruit and consent up to 34 participants		March – August 2018	Not started	0%
Subtask 2: Administer CQD-O, CQD-AF, and neurocognitive measures to up to 34 volunteers				
Subtask 2: Assure protocol fidelity and adherence to all IRB requirements		October 2017 – June 2018	Not started	0%
Enter data into study database.		Sept. 2017 – July 2018	Not started	0%
Major Task: Data Analysis & Dissemination				
Perform all analyses according to specifications, share output and finding with all investigators		August – Sept. 2018	Not started	0%
Work with data core and dissemination of findings (abstracts, presentation, publications, DOD)				

Projected Quarterly Enrollment

	Year 1				Year 2				Total
Target Enrollment (per quarter)	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	
Courage Kenny Research Center (Target)	-	-	2	-	-	4	20	14	40
Target Enrollment - Cumulative	-	-	2	-	-	6	26	40	40
Courage Kenny Research Center (Actual)			2						
Actual Enrollment - Cumulative			2						

What was accomplished under these goals?

For this reporting period describe: 1) major activities; 2) specific objectives; 3) significant results or key outcomes, including major findings, developments, or conclusions (both positive and negative); and/or 4) other achievements. Include a discussion of stated goals not met. Description shall include pertinent data and graphs in sufficient detail to explain any significant results achieved. A succinct description of the methodology used shall be provided. As the project progresses to completion, the emphasis in reporting in this section should shift from reporting activities to reporting accomplishments.

In Year 1, we have made progress on Technical Objective 1 (Develop a CQD-AF), which will be discussed for each set of subtasks.

Subtask 1: Establish contracts and critical documents for all participating institutions, contracts, and consultants.

In Year 1, Allina Health established a subaward with Colorado State University (Dr. Aaron Eakman) and contracts with consultants Dr. Tim Wolf and Dr. Leslie Davidson. All team members completed required CITI and COI training.

Subtask 2: Obtain Allina Health IRB and ORP/HRPO approval to conduct study.

In Year 1, protocols were submitted and approved by the Allina Health IRB and USAMRMC Human Research Protections Office for Part 1 of the study. Part 1 of the study involves recruiting/enrolling up to 6 adults, some with a history of acquired brain injury (ABI), who are willing to perform the CQD-Original (CQD-O) while being videorecorded and/or observed by researchers. The goal of doing so was to try to characterize the demands of the CQD-O in order to design a CQD-alternate form (CQD-AF) that has equivalent demands. The Allina Health approved the protocol on May 10, 2017 (expedited review). We received HRPO approval on July 7, 2017.

Goals not met: Once we have designed the CQD-AF, we will need to develop a Phase 2 IRB protocol related to the administration of the CQD-O, CQD-AF, and related neurocognitive measures to a sample of up to 34 adults (military, veteran, civilian, those with a mild TBI symptoms) and submit it to the Allina Health IRB and USAMRMC HRPO.

Subtask 3: Characterize CQD-Original

In Year 1, we developed a task analysis framework in an effort to characterize the task load of the CQD-O. The plan was to obtain team consensus on the CQD-O task load in order to replicate the task load in designing an equivalent CQD-AF. To that end, we first conducted experiential analyses in which each of the 6 occupational therapy investigators were administered the test. They then completed the task analysis form to describe their experience of task load. Experiential data from the 6 occupational therapists were analyzed by examining interrater reliability using Krippendorff's Alpha, which suggested that the 6 raters had different CQD task-load score patterns. Further analyses using box plots based on raters, task components, and task constructs continued to suggest task load largely varied by individual rather than task element. Overall, raters had some agreement that task load was greatest for cognitive elements and lowest for environmental demands. These analyses resulted in refinement of the task analysis framework/form so as to enhance clarity of task component definitions and rating scores.

Next we conducted observation-based task analyses of the CQD-O. CKRC investigators administered the CQD-O to two adults (one who was healthy, 1 with a history of ABI). Their performance was videorecorded and the 6 occupational therapy investigators reviewed the videorecorded performances and again used the task analysis to characterize the CQD-O task load. Efforts to develop a granular, singular task demand characterization using these methods were impeded by obvious participant differences in what aspects of the task they prioritized. For example, the healthy individual appeared to focus on making as few trips to work stations to complete the task, as stated explicitly in the instructions. Thus, this participant appeared to experience significant task stress associated with forethought and planning. However, the individual with a history of ABI appeared to focus on memory elements of the task, seemingly neglecting the instruction to make as few visits to work stations as possible (the planning component). These observations called into question the ability to characterize the task demands of the CQD-O separate from how individuals uniquely

experience the task, causing us to abandon our goal of developing a single ubiquitous, consensus-based task characterization of the CQD-O as preliminary to developing options for the CQD-AF. Instead, Tim Wolf, PhD, OTR/L developed a rubric that operationalizes various elements of the CQD-O, which will be used as the foundation for developing options for the CQD-AF.

Goals not met: In Year 1, we did not meet our goal of developing the CQD-AF to move forward to testing, though have completed preliminary steps to that end. Delays in preliminary contracting between Allina Health and subawards and consultants were contributing factors.

What opportunities for training and professional development has the project provided?

If the project was not intended to provide training and professional development opportunities or there is nothing significant to report during this reporting period, state “Nothing to Report.”

Describe opportunities for training and professional development provided to anyone who worked on the project or anyone who was involved in the activities supported by the project. “Training” activities are those in which individuals with advanced professional skills and experience assist others in attaining greater proficiency. Training activities may include, for example, courses or one-on-one work with a mentor. “Professional development” activities result in increased knowledge or skill in one’s area of expertise and may include workshops, conferences, seminars, study groups, and individual study. Include participation in conferences, workshops, and seminars not listed under major activities.

Nothing to report.

How were the results disseminated to communities of interest?

Describe how the results were disseminated to communities of interest. Include any outreach activities that were undertaken to reach members of communities who are not usually aware of these project activities, for the purpose of enhancing public understanding and increasing interest in learning and careers in science, technology, and the humanities.

Nothing to report.

What do you plan to do during the next reporting period to accomplish the goals?

Describe briefly what you plan to do during the next reporting period to accomplish the goals and objectives.

Goals and objectives	Planned activities for the next quarter
Subtask 4: Develop an optimal CQD-AF	-Create 2 subgroups that are charged with developing at least viable CQD-AF options by early Dec. 2017 -Subgroups are to develop task analyses for their 2 CQD-AF options.
Team work groups generate, develop options for CQD-AF	

Identify 2 best CQD-AF options; reduce to practice and informally administer (no formal data collection)	-Schedule an all-team TCON for early Dec. 2017 at which each group will present their 2 best CQD-AF options and task analyses (4 total). -Together the team will identify the 2 best options, reduce to practice, and informally prepilot.
Team consensus meeting to select optimal version of CQD-AF for subsequent evaluation and to finalize Phase 2 protocol	-Make decisions about team consensus meeting, tentatively scheduled for January 2018.

4. IMPACT: Describe distinctive contributions, major accomplishments, innovations, successes, or any change in practice or behavior that has come about as a result of the project relative to:

What was the impact on the development of the principal discipline(s) of the project?

If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how findings, results, techniques that were developed or extended, or other products from the project made an impact or are likely to make an impact on the base of knowledge, theory, and research in the principal disciplinary field(s) of the project. Summarize using language that an intelligent lay audience can understand (Scientific American style).

Nothing to Report.

Describe how the findings, results, or techniques that were developed or improved, or other products from the project made an impact or are likely to make an impact on other disciplines.

Nothing to Report.

What was the impact on technology transfer?

If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe ways in which the project made an impact, or is likely to make an impact, on commercial technology or public use, including:

- *transfer of results to entities in government or industry;*
- *instances where the research has led to the initiation of a start-up company; or*
- *adoption of new practices.*

Nothing to Report.

What was the impact on society beyond science and technology?

If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how results from the project made an impact, or are likely to make an impact, beyond the bounds of science, engineering, and the academic world on areas such as:

- *improving public knowledge, attitudes, skills, and abilities;*
- *changing behavior, practices, decision making, policies (including regulatory policies), or social actions; or*
- *improving social, economic, civic, or environmental conditions.*

Nothing to Report.

- 5. CHANGES/PROBLEMS:** The Project Director/Principal Investigator (PD/PI) is reminded that the recipient organization is required to obtain prior written approval from the awarding agency Grants Officer whenever there are significant changes in the project or its direction. If not previously reported in writing, provide the following additional information or state, “Nothing to Report,” if applicable:

Changes in approach and reasons for change

Describe any changes in approach during the reporting period and reasons for these changes.

Remember that significant changes in objectives and scope require prior approval of the agency.

As reported earlier, efforts to use experiential and observational task analyses to create a singular task-load characterization of the CQD-O yielded unanticipated results. We observed that task load varies, in part, with examinees’ perceptions/misperceptions of task instructions, thus interfering with the development of a singular, consensus-based CQD-O characterization of task load. Therefore, we adopted an alternative approach to developing options for a CQD-AF that have potentially equivalent task demands.

Actual or anticipated problems or delays and actions or plans to resolve them

Describe problems or delays encountered during the reporting period and actions or plans to resolve them.

As reported above, the contracting process took longer than anticipated. Allina Health is in the process of modifying/refining the processes, which may address this for future projects.

expenditures, for example, delays in hiring staff or favorable developments that enable meeting objectives at less cost than anticipated.

Nothing to report.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

Describe significant deviations, unexpected outcomes, or changes in approved protocols for the use or care of human subjects, vertebrate animals, biohazards, and/or select agents during the reporting period. If required, were these changes approved by the applicable institution committee (or equivalent) and reported to the agency? Also specify the applicable Institutional Review Board/Institutional Animal Care and Use Committee approval dates.

Significant changes in use or care of human subjects

None.

Significant changes in use or care of vertebrate animals.

N/A

Significant changes in use of biohazards and/or select agents

N/A

6. PRODUCTS: List any products resulting from the project during the reporting period. If there is nothing to report under a particular item, state “Nothing to Report.”

- **Publications, conference papers, and presentations**

Report only the major publication(s) resulting from the work under this award.

Journal publications. *List peer-reviewed articles or papers appearing in scientific, technical, or professional journals. Identify for each publication: Author(s); title; journal; volume; year; page numbers; status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

Nothing to Report

Books or other non-periodical, one-time publications. *Report any book, monograph, dissertation, abstract, or the like published as or in a separate publication, rather than a periodical or series. Include any significant publication in the proceedings of a one-time conference or in the report of a one-time study, commission, or the like. Identify for each one-time publication: Author(s); title; editor; title of collection, if applicable; bibliographic information; year; type of publication (e.g., book, thesis or dissertation); status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

Nothing to Report

Other publications, conference papers, and presentations. *Identify any other publications, conference papers and/or presentations not reported above. Specify the status of the publication as noted above. List presentations made during the last year (international, national, local societies, military meetings, etc.). Use an asterisk (*) if presentation produced a manuscript.*

Nothing to Report

- **Website(s) or other Internet site(s)**

List the URL for any Internet site(s) that disseminates the results of the research activities. A short description of each site should be provided. It is not necessary to include the publications already specified above in this section.

None.

- **Technologies or techniques**

Identify technologies or techniques that resulted from the research activities. In addition to a description of the technologies or techniques, describe how they will be shared.

Nothing to report.

- **Inventions, patent applications, and/or licenses**

Identify inventions, patent applications with date, and/or licenses that have resulted from the research. State whether an application is provisional or non-provisional and indicate the application number. Submission of this information as part of an interim research performance progress report is not a substitute for any other invention reporting required under the terms and conditions of an award.

None.

- **Other Products**

Identify any other reportable outcomes that were developed under this project. Reportable outcomes are defined as a research result that is or relates to a product, scientific advance, or research tool that makes a meaningful contribution toward the

understanding, prevention, diagnosis, prognosis, treatment, and/or rehabilitation of a disease, injury or condition, or to improve the quality of life. Examples include:

- *data or databases;*
- *biospecimen collections;*
- *audio or video products;*
- *software;*
- *models;*
- *educational aids or curricula;*
- *instruments or equipment;*
- *research material (e.g., Germplasm; cell lines, DNA probes, animal models);*
- *clinical interventions;*
- *new business creation; and*
- *other.*

None.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Provide the following information for: (1) PDs/PIs; and (2) each person who has worked at least one person month per year on the project during the reporting period, regardless of the source of compensation (a person month equals approximately 160 hours of effort). If information is unchanged from a previous submission, provide the name only and indicate “no change.”

Name:	Mary Vining Radomski
Project Role:	PD/PI
Researcher Identifier (e.g. ORCID ID):	0000-0003-0600-4494
Nearest person month worked:	1

Contribution to Project:	<p>Dr. Radomski contributed the following:</p> <ul style="list-style-type: none"> -Oversaw contracting with consultants and subawards -Developed and submitted the IRB protocol to Allina Health and USAMRMC -Worked with study coordinator to set up monthly team TCONs, facilitated meetings and distributed minutes -Contributed to development of task analysis methods -Performed task analyses on CQD-O
Funding Support:	This grant

There were no other individuals who contributed at least one person month over the past year. This is anticipated to change in Year 2 of the study.

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

If there is nothing significant to report during this reporting period, state “Nothing to Report.”

If the active support has changed for the PD/PI(s) or senior/key personnel, then describe what the change has been. Changes may occur, for example, if a previously active grant has closed and/or if a previously pending grant is now active. Annotate this information so it is clear what has changed from the previous submission. Submission of other support information is not necessary for pending changes or for changes in the level of effort for active support reported previously. The awarding agency may require prior written approval if a change in active other support significantly impacts the effort on the project that is the subject of the project report.

Changes in active support for the PD/PI:

- A previously active grant has closed of September 29, 2017 (Cognitive Rehabilitation: ACTION training for Soldiers with Executive Dysfunction; W81XWH-14-1-0198).
- Awarded funding for 2 new grants in the past year. The Purpose Project Feasibility Study (Engelsma Family Foundation) is in data-collection; The Purpose Project Efficacy Study (Abbott Northwestern Hospital Foundation) is on hold until the feasibility study is completed. These new projects are estimated to involve ~ 1-2 person months of PI/PD time in the coming year.

What other organizations were involved as partners?

If there is nothing significant to report during this reporting period, state “Nothing to Report.”

Describe partner organizations – academic institutions, other nonprofits, industrial or commercial firms, state or local governments, schools or school systems, or other organizations (foreign or domestic) – that were involved with the project. Partner organizations may have provided financial or in-kind support, supplied facilities or equipment, collaborated in the research, exchanged personnel, or otherwise contributed.

Provide the following information for each partnership:

Organization Name:

Location of Organization: (if foreign location list country)

Partner’s contribution to the project (identify one or more)

- *Financial support;*
- *In-kind support (e.g., partner makes software, computers, equipment, etc., available to project staff);*
- *Facilities (e.g., project staff use the partner’s facilities for project activities);*
- *Collaboration (e.g., partner’s staff work with project staff on the project);*
- *Personnel exchanges (e.g., project staff and/or partner’s staff use each other’s facilities, work at each other’s site); and*
- *Other.*

Nothing to report.

Development, Reliability, and Equivalence of an Alternate Form of the CQ Duty Performance-based Measure

ERMS/Log Number: BA150325

W81XWH-16-1-0581

PI: Mary Vining Radomski, PhD, OTR **Org:** Allina Health/Courage Kenny Research Center **Award Amount:** \$247,961.00



Study Aims

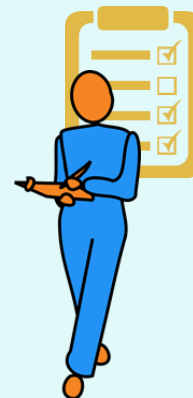
Technical Objective #1: Develop an alternate form of the CQD.

Technical Objective #2: Assure rater agreement across 2 raters in administering the CQD-Original (CQD-O) and CQD-Alternate Form

Technical Objective #3: Evaluate equivalence of CQD-AF based on a) difference of paired scores for both forms of the CQD and b) correlation between participants' performance of neurocognitive measures of executive functioning and each version of the CQD .

Approach

This study involves 2 parts. In part 1, a team of rehabilitation research experts from military, VA, civilian sectors will conduct task analyses of the CQD-O in order to characterize key demands. Based on the results, the team will develop 2 workable CQD-AF, conduct similar task analyses, and select the option that appears to be equivalent to the CQD-O. In part 2, 34 individuals (some with a history of mild TBI) will be recruited. Inter-rater agreement will be evaluated by 2 raters on the first 10-15 subjects. All subjects will perform CQD-O, CQD-AF, and neurocognitive measures to assess construct validity.



Performance-based measures that involve multitasking appear to be sensitive to deficient executive functions that can occur with TBI; this type of test can't be repeated due to practice effects. The CQD test, part of the recently developed *Assessment of Military Multitasking Performance*, was found to be reliable and differentiate between healthy controls and SM with mild TBI. **If we succeed in developing an equivalent alternate form, the CQD may be used to both identify executive dysfunction and quantify treatment outcomes in SM with mTBI.**

Accomplishments (Yr1, Q4): Obtained approval from USAMRMC HRPO; recruited/enrolled participants and conducted observational task analyses of CQD-O. Based on results of the above, further refined task analysis methodology used to frame CQD-O task demands to inform development of CQD-AF options.

Timeline and Cost

Activities	CY	16	17	18	19
Establish contracts; prepare for task analyses; submit Part 1 protocol to Allina IRB					
Develop CQD-AF					
Conduct validation study on CQD-AF					
Data analysis and dissemination					
Estimated Budget (\$K)		\$10	\$130	\$107	\$0

Goals/Milestones

CY16 Goal – Study kick off

- ☒ Functionality tests of integrated firmware and software
- ☒ Development and submission of Part 1 protocol to Allina IRB
- ☒ Obtain approval from Part 1 protocol to USAMRMC HRPO

CY17 Goals – Develop CQD-AF; begin validation study

- ☒ Conduct task analyses to characterize CQD-O
- ☐ Develop CQD-AF options; select best option to subject to validation
- ☐ Obtain IRB approval for Part 2 of study (CQD-AF validation)
- ☐ Begin subject enrollment, data collection for validation study (part 2)

CY18 Goal – Complete validation study; analyze/report findings

- ☐ Complete subject enrollment, data collection for validation study
- ☐ Analyze data
- ☐ Report findings

Comments/Challenges/Issues/Concerns

We experienced contract- and IRB-related delays that have slowed the study progress in Year 1.

Budget Expenditure to Date

Projected Total Expenditure: \$247,961.00

Actual Expenditure: \$35,304.87

Updated: 9/30/17